

# SCANTIBODIES LABORATORY, INC.

"SCANTIBODIES FOR ANTIBODIES"

K95513 MAR 12 1996

## 510(k) Summary

**Submitter:** Tom Cantor  
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**Date:** December 15, 1995

**Device Name:** SysCon (or other brand names) Tumor Marker Control

**Predicate Device:** Dade® Special-T™ Marker, manufactured by Baxter Diagnostics Inc.

### Device Description:

This is a two level, multi-analyte, lyophilized quality control material prepared from human blood, with added purified chemicals, human biochemicals and preservatives.

### Intended use:

For use as an assayed quality control material to assist in monitoring accuracy and precision in clinical immunoassays used in cancer antigen testing.

**Comparison of the product to the predicate device** for intended use, analytes, number of levels, form, diluent, base, additives, microbial content, lot homogeneity and vial-to-vial consistency, stability and reliability of assay values supports a substantial equivalence finding.

### Performance data:

Nonclinical tests for vial-to-vial variability, reconstituted stability and expiration dating, as well as value assignment protocols, submitted, referenced, or relied on in the premarket notification submission, support the conclusion that the device is as safe and effective, and performs as well as or better than the legally marketed devices identified in this summary.